



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,446	12/20/2001	Daniel M. Cimora	2318-279-II	2282

6449 7590 02/25/2004

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9-AM

Office Action Summary	Application No. 10/023,446	Applicant(s) CIMBORA ET AL.	
	Examiner Celine X Qian	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-160 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-160 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-160 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a protein complex, classified in class 530, subclass 402.
- II. Claims 5, 6, 155, 156, drawn to an antibody, classified in class 530, subclass 387.1.
- III. Claims 7-16, drawn to a method of diagnosing a physiological disorder by assaying the presence of a protein complex, class 530, subclass 350.
- IV. Claims 17-26, drawn to a method of determining whether a mutation is useful for diagnosing a physiological disorder, class 536, subclass 23.1.
- V. Claims 27-30, drawn to a non-human animal disease model in which the genome is altered, class 800, subclass 9.
- VI. Claims 31-37, drawn to a non-human animal disease model in which the biological activity of a protein complex is altered, class 800, subclass 13.
- VII. Claims 38-45, drawn to a cell or cell line comprising the protein complex or nucleic acid expressing a first protein and a second protein, class 435, subclass 325.
- VIII. Claims 46-52, drawn to a method of screening for drug candidates capable of modulating the interaction of a protein complex, class 530, subclass 402.
- IX. Claims 53-55, drawn to a method of screening drugs useful in treating a physiological disorder, class 424, subclass 178.1.

- X. Claims 56-58, 84-88, drawn to a method for selecting modulators of a protein complex by determining the binding of the test compound to the protein, class 530, subclass 806.
- XI. Claims 59-70 drawn to a method for selecting modulators of an interaction between two proteins or a protein complex by determining the interaction between proteins in the presence of a test compound, class 530, subclass 402.
- XII. Claims 71-74, drawn to a method for selecting modulators of an interaction between two polypeptides by using cells, class 424, subclass 94.1.
- XIII. Claims 75-77, drawn to a method for identifying a compound that binds to a protein *in vivo*, class 424, subclass 130.1.
- XIV. Claims 78-80, drawn to a method for selecting modulators of an interaction between two polypeptides by using atomic coordinates, class 530, subclass 402.
- XV. Claims 81-83, drawn to a method for providing inhibitors of an interaction between two polypeptide, class 424, subclass 178.1.
- XVI. Claims 89-95, 113-116, drawn to a method for modulating a protein complex in a cell, class 435, subclass 325.
- XVII. Claims 96-102, a method for modulating neuronal death in a patient having a physiological disorder, class 514, subclass 44.
- XVIII. Claims 103-112, drawn to a method for treating a physiological disorder by administering a compound that is capable of modulating a protein complex, class 424, subclass 178.1.

XIX. Claims 117-143 and 160, drawn an isolated nucleic acid, host cells comprising said nucleic acid and method of making a protein by culturing the host cell, class 435, subclass 320.1 and 254.2.

XX. Claim 144, drawn to a nucleic acid miroarray, unclassifiable.

XXI. Claims 145-154, drawn to isolated polypeptide, unclassifiable.

XXII. Claims 157-159, drawn to protein microarray, class 530, subclass 350.

The inventions are patentably distinct, each from the other for following reasons.

The inventions of Groups I, II, V-VII, XIX-XXII are patentably distinct from each other because the inventions are drawn to materially distinct compositions that are not directly related. The inventions of these groups are chemically, biologically and functionally distinct from each other. Therefore, the inventions of Groups I, II, V-VII, XIX-XXII are patentably distinct.

The inventions of Groups III, IV, VIII-XVIII are patentably distinct from each other because the inventions are drawn to methods that requires different starting materials and modes of operation. Each method comprises distinct method steps and has different purposes. Therefore, the inventions of Groups III, IV, VIII-XVIII are patentably distinct.

The inventions of Groups I, II, V-VII, XIX-XXII are patentably distinct from the inventions of Groups III, IV, VIII-XVIII because they are drawn to compositions and methods that are not directly related. The methods of Groups III, IV, VIII-XVIII do not require the compositions of Groups I, II, V-VII, XIX-XXII. Therefore, the inventions are patentably distinct.

Groups XIX-XXII are comprised of multiple inventions which are the products drawn to different and distinct sequences which do not render obvious each other and thus are patentably

Art Unit: 1636

distinct. If any of Groups XIX-XXII are elected, applicants must elect a single invention which is the product drawn to one specific sequence to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results.

Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER